



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,842	08/04/2003	Keith Rosiello	350930-0200 (ZQI-127/US)	5671
48329	7590	05/28/2008	EXAMINER	
FOLEY & LARDNER LLP 111 HUNTINGTON AVENUE 26TH FLOOR BOSTON, MA 02199-7610			SORKIN, DAVID L	
			ART UNIT	PAPER NUMBER
			1797	
			MAIL DATE	DELIVERY MODE
			05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/633,842	ROSIELLO, KEITH	
	Examiner	Art Unit	
	David L. Sorkin	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-6, 8, 9, 11, 12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 8, 9, 11, 12 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4-6, 8, 9, 11, 12 and 14-20 rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/28451. Regarding claim 1, WO '451 discloses a flexible centrifugal chamber (31,32,41,42,71,72,81 or 82; or a plurality of adjacent, connected bags such as E-E) comprising a first circular side wall (for example, considering flexible chamber 32 as depicted in Fig. 3, the first side wall may be considered the left side of the hub; and, in another example, considering two adjacent, connected bags, one of the two outer side walls) with an axial opening (such as 23 or 63) and a second side wall (for example, considering flexible chamber 32 as depicted in Fig. 3, the second side wall may be considered the right side of the hub; and, in another example, considering two adjacent, connected bags, the other of the two outer side walls) with an axial opening (such as 23 or 63), and an expandable wall (for example, the two flexible plastic circular sheets of a single bag; or in another example, two adjacent sheets of two adjacent connected bags) extending between an outer circumference of each of the first and second circular side walls, wherein a first end of the expandable wall is attached to the outer circumference of the first circular side wall of the flexible chamber and a second end of the expandable wall is attached to the outer circumference of the opposing

second side wall of the flexible chamber (see for example Fig. 3), wherein the expandable wall includes at least one pair of corresponding partitions (for example the left and right halves of the expandable wall of 32 as depicted in Fig. 3; in other words the “two sheets of flexible material” mentioned on page 3, lines 9-11; and in another example two adjacent sheets of two adjacent connected bags, one from each bag), a first partition of one of the at least one pair of partitions including a first circumferential end attached to the outer circumference of the first circular side wall, a second partition of one of the at least one pair of partitions including a second circumferential end attached to the outer circumference of the second circular side wall of the flexible chamber (see Fig. 3; page 3, lines 9-11), wherein the chamber is sterilized (see page 1, lines 11-13; page 5, line 25), having a variable volume capacity and adaptable to a continuous centrifuge (see page 2, lines 5-6). Regarding claim 4, the flexible chamber comprises a processing chamber (see page 6, lines 2-5). Regarding claim 5, the flexible chamber comprises an expressor chamber (see page 6, lines 2-5). Regarding claim 6, the expandable wall comprises an accordion wall (see Fig. 9). Regarding claim 8, the expandable wall includes a plurality of pairs of partitions (see Fig. 9). Regarding claims 9 and 11, WO ‘451 discloses a processing apparatus comprising a centrifugal chamber (31,32,41,42,71,72,81 or 82; or a plurality of adjacent, connected bags such as E-E) comprising a first circular side wall (for example, considering flexible chamber 32 as depicted in Fig. 3, the first side wall may be considered the left side of the hub; and, in another example, considering two adjacent, connected bags, one of the two outer side walls) with an axial opening (such as 23 or 63) and a second side wall (for

example, considering flexible chamber 32 as depicted in Fig. 3, the second side wall may be considered the right side of the hub; and, in another example, considering two adjacent, connected bags, the other of the two outer side walls) with an axial opening (such as 23 or 63), and an expandable wall (for example, the two flexible plastic circular sheets of a single bag; or in another example, two adjacent sheets of two adjacent connected bags) extending between an outer circumference of each of the first and second circular side walls, wherein a first end of the expandable wall is attached to the outer circumference of the first circular side wall of the flexible chamber and a second end of the expandable wall is attached to the outer circumference of the opposing second side wall of the flexible chamber (see for example Fig. 3), wherein the expandable wall includes at least one pair of corresponding partitions (for example the left and right halves of the expandable wall of 32 as depicted in Fig. 3; in other words the “two sheets of flexible material” mentioned on page 3, lines 9-11; and in another example two adjacent sheets of two adjacent connected bags, one from each bag), a first partition of one of the at least one pair of partitions including a first circumferential end attached to the outer circumference of the first circular side wall, a second partition of one of the at least one pair of partitions including a second circumferential end attached to the outer circumference of the second circular side wall of the flexible chamber (see Fig. 3; page 3, lines 9-11), wherein the chamber is sterilized (see page 1, lines 11-13; page 5, line 25), having a variable volume capacity and adaptable to a continuous centrifuge (see page 2, lines 5-6). Regarding claim 12, the expandable wall is an accordion wall (see Fig. 9). Regarding claim 14, the expandable wall includes a

plurality of pairs of partitions (see Fig. 9). Regarding claim 15, the flexible chamber comprises a processing chamber (see page 6, lines 2-5). Regarding claim 16, the flexible chamber comprises an expressor chamber (see page 6, lines 2-5). Regarding claim 17, there are plural flexible chambers (see page 6, lines 2-28). Regarding claim 18, the apparatus has a processing chamber and an expressor chamber (see page 6, lines 2-28). Regarding claim 19, WO '451 discloses a continuous flow centrifuge (see page 2, lines 5-6) comprising a first circular side wall (for example, considering flexible chamber 32 as depicted in Fig. 3, the first side wall may be considered the left side of the hub; and, in another example, considering two adjacent, connected bags, one of the two outer side walls) with an axial opening (such as 23 or 63) and a second side wall (for example, considering flexible chamber 32 as depicted in Fig. 3, the second side wall may be considered the right side of the hub; and, in another example, considering two adjacent, connected bags, the other of the two outer side walls) with an axial opening (such as 23 or 63), and an expandable wall (for example, the two flexible plastic circular sheets of a single bag; or in another example, two adjacent sheets of two adjacent connected bags) extending between an outer circumference of each of the first and second circular side walls, wherein a first end of the expandable wall is attached to the outer circumference of the first circular side wall of the flexible chamber and a second end of the expandable wall is attached to the outer circumference of the opposing second side wall of the flexible chamber (see for example Fig. 3), wherein the expandable wall includes at least one pair of corresponding partitions (for example the left and right halves of the expandable wall of 32 as depicted in Fig. 3; in other words

the “two sheets of flexible material” mentioned on page 3, lines 9-11; and in another example two adjacent sheets of two adjacent connected bags, one from each bag), a first partition of one of the at least one pair of partitions including a first circumferential end attached to the outer circumference of the first circular side wall, a second partition of one of the at least one pair of partitions including a second circumferential end attached to the outer circumference of the second circular side wall of the flexible chamber (see Fig. 3; page 3, lines 9-11), wherein the chamber is sterilized (see page 1, lines 11-13; page 5, line 25), having a variable volume capacity and adaptable to a continuous centrifuge (see page 2, lines 5-6). Regarding claim 20, WO ‘451 discloses a biological cell processing apparatus comprising a continuous flow centrifuge (see page 2, lines 5-6) and a sterilized (see page 1, lines 11-13; page 5, line 25) flexible centrifugal chamber (31,32,41,42,71,72,81 or 82; or a plurality of adjacent, connected bags such as E-E) comprising a first circular side wall (for example, considering flexible chamber 32 as depicted in Fig. 3, the first side wall may be considered the left side of the hub; and, in another example, considering two adjacent, connected bags, one of the two outer side walls) with an axial opening (such as 23 or 63) and a second side wall (for example, considering flexible chamber 32 as depicted in Fig. 3, the second side wall may be considered the right side of the hub; and, in another example, considering two adjacent, connected bags, the other of the two outer side walls) with an axial opening (such as 23 or 63), and an expandable wall (for example, the two flexible plastic circular sheets of a single bag; or in another example, two adjacent sheets of two adjacent connected bags) extending between an outer circumference of each of the first and

second circular side walls, wherein a first end of the expandable wall is attached to the outer circumference of the first circular side wall of the flexible chamber and a second end of the expandable wall is attached to the outer circumference of the opposing second side wall of the flexible chamber (see for example Fig. 3), wherein the expandable wall includes at least one pair of corresponding partitions (for example the left and right halves of the expandable wall of 32 as depicted in Fig. 3; in other words the “two sheets of flexible material” mentioned on page 3, lines 9-11; and in another example two adjacent sheets of two adjacent connected bags, one from each bag), a first partition of one of the at least one pair of partitions including a first circumferential end attached to the outer circumference of the first circular side wall, a second partition of one of the at least on pair of partitions including a second circumferential end attached to the outer circumference of the second circular side wall of the flexible chamber (see Fig. 3; page 3, lines 9-11).

3. Claims 1, 4-6, 8, 9, 11, 12 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Knoll et al. (US 5,242,398). Regarding claim 1, Knoll ('398) discloses a flexible chamber (portion 32 of sheet 24, in other words the series of pleats 28) comprising a first circular side wall (in Fig. 1, the left-most pleat 28, in other words, the portion at the end of the lead-line for “32”) with an axial opening and a second, opposing circular side wall (in Fig 1, the right-most pleat 28) with an axial opening, and an expandable wall (in Fig. 1, all the pleats 28, except for the left-most and right-most) extending between an outer circumference of each of the first and second opposing circular side walls, wherein the expandable wall is attached to the outer circumference

of the first circular side wall of the flexible chamber and a second end of the expandable wall is attached to a circumference of the second side of the flexible chamber, wherein the expandable wall includes at least one pair of corresponding partitions (two adjacent pleats 28), a first partition of one of the at least one pair of partitions including a first circumferential end attached to the outer circumference of the first circular side wall of the flexible chamber and a second partition of one of the at least one pair of partitions including a second circumferential end attached to the outer circumference of the second circular side wall (see Fig. 1), wherein the chamber is sterilized (see col. 1, lines 5-10; col. 3, line 55) and has a variable volume capacity. While the reference does not involve a centrifuge, a centrifuge is not part of the claimed structure and “the manner or method in which such machine is to be utilized is not germane to the issue of patentability of the machine itself” *In re Casey*, 152 USPQ 235 (CCPA 1967).

Regarding claim 4, the flexible chamber comprises a processing chamber (see Fig. 1). Regarding claim 5, the flexible chamber comprises an expressor chamber (see Fig. 1). Regarding claim 6, the expandable wall comprises an accordion wall (see col. 5, lines 59-67). Regarding claim 8, the expandable wall includes a plurality of pairs of partitions (see Fig. 1; col. 5, lines 59-67). Regarding claims 9 and 11, Knoll ('398) discloses processing apparatus comprising a flexible chamber (portion 32 of sheet 24, in other words the series of pleats 28) comprising a first circular side wall (in Fig. 1, the left-most pleat 28, in other words, the portion at the end of the lead-line for “32”) with an axial opening and a second, opposing circular side wall (in Fig 1, the right-most pleat 28) with an axial opening, and an expandable wall (in Fig. 1, all the pleats 28, except for the left-

most and right-most) extending between an outer circumference of each of the first and second opposing circular side walls, wherein the expandable wall is attached to the outer circumference of the first circular side wall of the flexible chamber and a second end of the expandable wall is attached to a circumference of the second side of the flexible chamber, wherein the expandable wall includes at least one pair of corresponding partitions (two adjacent pleats 28), a first partition of one of the at least one pair of partitions including a first circumferential end attached to the outer circumference of the first circular side wall of the flexible chamber and a second partition of one of the at least one pair of partitions including a second circumferential end attached to the outer circumference of the second circular side wall (see Fig. 1), wherein the chamber is sterilized (see col. 1, lines 5-10; col. 3, line 55) and has a variable volume capacity. While the reference does not involve a centrifuge, a centrifuge is not part of the claimed structure and “the manner or method in which such machine is to be utilized is not germane to the issue of patentability of the machine itself” *In re Casey*, 152 USPQ 235 (CCPA 1967). Regarding claim 12, the expandable wall is an accordion wall (see col. 5, lines 59-67). Regarding claim 14, the expandable wall includes a plurality of pairs of partitions (see Fig. 1; col. 5, lines 59-67). Regarding claim 15, the flexible chamber comprises a processing chamber (see Fig. 1). Regarding claim 16, the flexible chamber comprises an expressor chamber (see Fig. 1). Regarding claim 17, there are plural flexible chambers (each being a section of sheath 24). Regarding claim 18, the apparatus has a processing chamber and an expressor chamber (each being a section of sheath 24).

Response to Arguments

4. WO 02/28451 anticipates the instant claims in more than one way. The chambers of WO '451 are not just the two flexible sheets so material which are joined at their outer circumferences, but also include opposing circular walls, which are part of the hubs. The flexible sheets each constitute a partition, and each is joined to an outer circumference of a respective circular wall. The two joined partitions, form an expendable wall which extends between the two opposed circular walls.

5. In another exemplary manner in which WO '451 anticipates the claims, two or more sub-chambers (such as E-E) read on a chamber recited in the claims. In this example, there will be a total of at least 4 flexible sheets for each claimed chamber. The two outermost sheets, and optionally including portions of hub(s), are the circular walls which are claimed, while the two or more inner flexible sheets read on the expandable side wall element of the claims.

6. Knoll ('398) has not been relied upon to reject any claim that requires a centrifuge, or a step involving a centrifuge. However, Knoll ('398) may properly be relied upon when applicant is not claiming a centrifuge, for example when only a chamber is being claimed. Contrary to applicant's remarks, "Arguments that the alleged anticipatory prior art is 'nonanalogous art' or 'teaches away from the invention' or is not recognized as solving the problem solved by the claimed invention, [are] not 'germane' to a rejection under section 102." *Twin Disc, Inc. v. United States*, 231 USPQ 417, 424 (Cl. Ct. 1986) (quoting *In re Self*, 213 USPQ 1, 7 (CCPA 1982)). In the current grounds for rejection, cup part 30 of Knoll ('398) is not relied upon. Instead, the first and last

pleats are considered to be the first and second circular walls. Applicant's remarks do not address this aspect of the grounds of rejection of the currently amended claims.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 571-272-1148. The examiner can normally be reached on 7:30-4:00 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David L. Sorkin/

David L. Sorkin
Primary Examiner
Art Unit 1797

DLS